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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,497	05/01/2001	Amina Odidi	9577-25 LAB	2340

7590

06/17/2004

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CANADA

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/845,497

**Applicant(s)**

ODIDI ET AL.

**Examiner**

Alton N. Pryor

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,6-9,11,15-17 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,6-9,11,15-17,21-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's arguments filed 3/8/04 have been fully considered but they are not persuasive. See arguments below.

- I. Rejection of claims 1,6-9,11,15-17,21-34 under 35 USC 112, 2<sup>nd</sup> will not be maintained. The term "extrusion aid" is known in the art.
- II. Rejection of claims 1,6-9,17,21,23,26,30-33 under 35 USC 103(a) as being obvious over Cheng will be maintained for reason on record and reason as follows.

Applicant argues that Cheng teaches a core of active coated with a semi-permeable membrane. Cheng teaches that the membrane is permeable to the passage of external fluids such as water and is impermeable to the passage of the drug in the core. As such, Applicant argues that the semi-permeable membrane does not dissolve at alkaline pH due to the fact that Cheng uses different polymers than those of instant invention. Applicant argues that Cheng uses non-enteric cellulose esters (cellulose acetate). Examiner argues that the instant invention is open to Cheng's polymers since instant claims do not specifically name polymers. Examiner argues that instant claims do not state whether the polymers are non-enteric or enteric. Furthermore, Examiner argues that Cheng discloses that the semi permeable membrane is formed from 50-90% polymers (cellulose acetate), PEG, and plasticizer which are also acceptable components of the instant claims. For this reason, it would have been obvious to expect the prior art invention (semi permeable membrane) to be soluble at pH above 5.0.

Applicant argues that Cheng does not teach an encasement coat comprising a polymeric film (cellulose ester) encasing an active wherein the coat comprises 5-50%

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polymer and 0.5-30% PEG. Examiner argues that Cheng teaches an encasement coat comprising a polymer film (cellulose acetate) encasing an active wherein the coat comprises 50-90% polymer and 0-25% PEG. Examiner argues that Cheng's amount of PEG overlaps the amount of PEG disclosed by the instant invention. It is very possible that the optimum amount of PEG could fall at a point that is within both the prior art and instant invention range. Examiner argues that although the instant invention teaches 50-90 % polymer and that the instant invention teaches less than 50% polymer, the Applicant does not show unexpected data for Cheng's coating having 49% polymer. Examiner encourages Applicant to write claims more in line with unexpected data.

***New Matter in Specification***

The amendment filed 3/8/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "extrusion aid may be microcrystalline cellulose".

Applicant is required to cancel the new matter in the reply to this Office Action.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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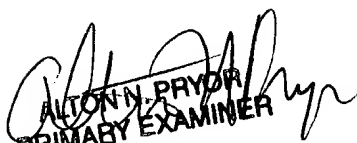
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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PRIMARY EXAMINER  
Alton Pryor  
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AU 1616